Amend the application as follows:

IN THE CLAIMS

Add the following claims:

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--7. A process according to claim 2 wherein the carbon dioxide is supercritical carbon dioxide.--

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--8. A process according to claim 2 wherein the carbon dioxide is liquid carbon dioxide.--

REMARKS

Claims 7 and 8 individually cover the specific types of carbon dioxide of claim 2. Hence, support can be found in claim 2 as filed. It is submitted that the claims presented do not introduce new matter. Entry and approval of the same respectfully is solicited.

Claims 1-6 stand rejected under 35 USC §103(a) as being unpatentable over Zhang, *et al.*, (CA 113:198104, abstract of Zhongguo Yiyao Gongye Zazhi (1990), 21(6), 256-61) ("Zhang") in view of Lee, *et al*, (CA 124:105153, abstract of J. Microcolumn Sep. (1995), 7(5):477-83) ("Lee"). (Office Action, p. 3, first paragraph). For the reasons presented below, reconsideration and withdrawal of the rejection is solicited.

Zhang discloses an HPLC determination of a "Vitamin D preparation," wherein a heated Vitamin D_3 solution was irradiated by UV, having a main wave length of 254 and 365 nm, for 5 minutes. (Zhang at AB.) Following irradiation, "6 isomers" were separated using normal-phase HPLC with a Waters Resolve Silica column and 0.3% n-pentanol in hexane as the mobile phase with detection at 254 nm having a resolution factor of greater than 1.0. (*Id.*) Reportedly,

the low concentration preparation could be detected by an internal method, di-Me phthalate, or an external method, thermal equil., with 10% error. (*Id.*) The error in detection of the high concentration preparation was 3%. (*Id.*)

Lee discloses applications of reversed-phase HPLC using "enhanced-fluidity liquid mobile phases." (Lee at AB). Reportedly, these mobile phases (methanol /H_2O/CO_2) were used as eluents. (*Id.*) Lee also discloses that the "low pressure drop across the column allowed serial connection of micro-scale columns to achieve the efficient separation of a coal tar sample." (*Id.*) The reference states that "[o]ther applications such as the separation of fat soluble vitamins . . . are shown." (*Id.*)

In making the rejection, the Examiner relied on Zhang's disclosure of "the separation of 6 isomers separated by using irradiation technique and the purification on silica column (stationary phase)." (Office Action, p. 3, third paragraph).

The Examiner acknowledged, however, that the "[i]nstant claims differ from [Zhang] in claiming the liquid CO_2 for separation by column chromatography using liquid CO_2." (*Id.*)

To fill the acknowledged gap, the Examiner relied on Lee as "alleviat[ing] this deficiency by teaching the separation of coal tar, vitamins, and other related compounds. The enhance fluidity liquid mobile phase contains methanol/H_2O/CO_2 are used in a column." (*Id.*)

The Examiner then contended that it would have been obvious to combine the references because "they are from the same field of endeavor" and that there is "[n]othing unobvious to separate the vitamin D as instantly claimed by the process known in the art." (*Id.* at 4).

Initially, with all due respect, it appears that the Examiner has overlooked recitations in claim 1 and, hence, all claims, since claims 2-6 depend from claim 1. Claim 1 recites, among other things, "**vitamin D_3 or previtamin D_3** ***from mixtures with other components,***" and "***separating*** the vitamin D_3 and previtamin D_3." Zhang does not disclose, much less suggest separating vitamin D_3 or previtamin D_3 from mixtures with other compnents.

Hence, because neither of the references of the rejection contain the requisite factual basis required under 35 USC § 103(a), the rejection of all claims should be withdrawn for this reason alone. *See Uniroyal Inc. v. Rudkin-Wiley Corp.*, 5 USPQ2d 1434,1439 (Fed Cir. 1988).

Moreover, the Examiner's reasoning that the references are combinable "because they are from the same field of endeavor" cannot stand. Even when references are in related fields, the Examiner still has the burden of establishing (1) that there is a suggestion or motivation to combine the references relied upon, and (2) that the references, when so combined, contain the requisite suggestion and motivation that would have led one to combine the particular disclosure relied upon and to make the process or composition as claimed. *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Moreover, the Examiner's contention for combining Zhang and Lee falls far short of presenting the requisite factual basis, requisite reason, suggestion, or motivation to do what the applicant has done and to arrive at the process as is claimed. *See* MPEP §2141 and §2145(j)(3). "When relying on numerous references or a modification of prior art, it is incumbent upon the examiner to identify some suggestion to combine references or make the modification." *In re Mayne*, 41 USPQ2d 1451, 1545 (Fed. Cir. 1997).

In addition, the Examiner did not identify any reason, suggestion, or motivation to combine Zhang and Lee other than being in the same "field of endeavor." The Examiner failed to present any reasoning or explanation as to why one of ordinary skill in the art would have been motivated to use normal-phase HPLC determination of Vitamin D preparations, as disclosed by Zhang, with reverse-phase HPLC using enhanced fluidity liquid mobile phases of Lee. Absent any such facts or evidence, the rejection cannot stand and should be withdrawn. Obviousness, must be based on facts. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993). When a rejection under § 103 is not based on facts, it can not stand. *Ex parte Porter*, 25 USPQ2d 1144, 1147 (BPAI 1992).

Turning to claim 7, both references disclose analytical separations by using HPLC. The separation in each is effected with a liquid eluent. However, in claim 7, the supercritical CO_2 is not in liquid phase. In HPLC, thermodynamical conditions are relevant, which are entirely different from the situation, in which the mobile phase is in the supercritical state. Thus, with respect to claims requiring the use of supercritical CO_2, the Examiner has not met his burden.

Regarding claim 8, Lee uses a highly polar aqueous eluent, which cannot be compared with the highly non-polar liquid CO_2 phase in the process of claim 8 because the two types of eluents show an entirely different separation behavior. According to Lee, only a small quantity of CO_2 is added for lowering the viscosity of the aqueous eluent. From this, one cannot derive any suggestion towards a possible usefulness of pure CO_2 or of liquid CO_2 with a small modifier content for the separation of vitamin D_3 isomers. Nor has the Examiner contended as such. Thus, the Examiner has further failed to meet his burden. Therefore, for this reason the rejection cannot stand and should be removed.

Further, the Examiner asserts that determining the size and shape of the silica gel particles (claim 4) and use thereof as a stationary phase (claim 5) would "have been within the skills familiar with the art." (Office Action, p. 4). However, "both the suggestion and the expectation of success must be found in the prior art, not in the applicants disclosure." *In re Dow Chem.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). There is no suggestion or motivation in any cited reference, for determining the size and shape of the silica gel, much less for the use of silica gel as a stationary phase to prepare vitamin D_3. For this reason the rejection cannot stand and it should be withdrawn.

Finally, the Examiner suggested that the submission of "data showing unexpected results would overcome the 35 U.S.C. §(a) rejection." (Office Action, p. 5). Because the Examiner has not made a *prima facie* case of obviousness, no such showing is required at this time.

For all of the foregoing reasons, withdrawal of the rejection and allowance of all claims respectfully is requested.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, on March 14, 2000.

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Respectfully submitted,

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